Department of Health and Mental Hygiene
Laboratories Administration

MJ02.01
FY 2004

Overview

The primary responsibility of the Laboratories Administration is to provide laboratory-testing services to support the core functions of public health.

Major Programs

1. Assist the Department to protect the people in Maryland against the spread of communicable and infectious diseases by identifying the cause of disease outbreaks, and by continuous laboratory-based disease surveillance; monitor emergence of antibiotic/drug resistant strains of infectious disease agents and laboratory monitoring for the emergence and reemergence of infectious disease agents in the State; maintain capability to detect bioterrorism events involving release of infectious agents.

2. Protect the health of the public from food products and consumer products which may cause injury or illness and to identify substandard sanitation practices in food establishments and food processing facilities by conducting laboratory analysis for food quality and food safety. Maintain an emergency response capacity to assess the extent of radioactive contamination of the food supply and the environment in the event of a radiological accident.

3. Enforcement of the Controlled Dangerous Substances Act, and the Food, Drug and Cosmetic Act to regulate the sale and distribution of controlled dangerous substances to assure their availability for legitimate medical and scientific purposes and to prevent abuses which could result in serious health problems. The Administration works closely with the Board of Physician Quality Assurance, the Board of Pharmacy, and the U.S. Drug Enforcement Administration to carry out the intent of these Acts.

4. Public health prevention of hereditary and congenital defects that could lead to mental retardation, other disabilities or death if not detected very early in life and appropriately treated. This prevention program consists of screening blood spot specimens collected from all newborn babies in Maryland to detect several inherited disorders.

5. Provide laboratory services needed to support enforcement and surveillance activities of State and local health department programs, the Department of the Environment, Department of Natural Resources, State Athletic Commission, State Anatomy Board, State Medical Examiner's Office and other State agencies for special needs.

6. Assure for the public that medical laboratory services provided by hospital laboratories, commercial laboratories, physician office labs, blood banks and tissue banks are safe and reliable by developing standards and regulations for enforcement by the Division of Licensure and Certification.

7. Certify environmental laboratories that test potability of public drinking water supplies; certify chemists/analysts in State, county and city crime labs who test controlled dangerous substances and approve procedures used for testing.

8. Develop and maintain laboratory emergency preparedness capability for biological, chemical and radiological terrorism and for natural disasters.

9. The Administration works closely with other State, local, and federal agencies to carry out its duties and responsibilities to the residents of Maryland.

Program Achievements

Bioterrorism

Grants received from the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Justice allowed the Laboratories Administration to expand its capability to detect and identify many more potential bioterrorism agents and to expand the ability of staff to rapidly identify agents using genetic techniques.

Methods are being developed to test the food supply, public drinking water, air and other environmental samples to detect intentionally introduced bioterrorism agents.

Hands-on training was conducted for hospital laboratory microbiologists in the State to serve as part of the State's Laboratory Response Network (LRN). If hospital laboratories recover a suspicious infectious agents, it is referred to the State Public Health Laboratory where reagents and techniques are available to confirm the agents.

Bioterrorism conferences were held to educate and unite state resources in case of an event. A conference was held for first responders (FBI, Maryland State Police, local police, fire departments, HAZMAT groups, MEMA, MEIMSS, universities, hospitals and the epidemiology community). Also, a bioterrorism conference was held for environmentalists and sanitarians to improve working relationship and to discuss operational plan of the Laboratories Administration.

A quarterly Bioterrorism Newsletter was published and distributed to local health departments, hospitals, clinical labs, veterinary labs, various state agencies and individuals who are part of the State emergency preparedness and response network to keep them informed on the important issues related to potential agents, collection of samples, safe packaging and transport to the public health lab.

Implemented HB-361 Biological Agents Registry which became effective November 25, 2002. Registration forms with copies of Rules and Regulations (COMAR 10.10.11) were mailed to 450 prospective entities.

Received a CDC grant for chemical terrorism to equip lab to conduct biomonitoring of potentially exposed individuals and a grant from FEMA to analyze body fluids of individuals who may have been exposed to war gases (Total $471,000).

Completed a laboratory operational plan for Chemical Terrorism and Radiological Terrorism.

During calendar year 2002 suspected bioterrorism samples received and tested by the Laboratory averaged 30 samples per month (total 356 samples for the year), and these samples were delivered by the FBI.

Training courses for hospital lab personnel are being planned for late January and early March to familiarize them with potential bioterrorism agents which they may recover from patients and the need to refer these isolates to the Public Health Laboratory for confirmation and genetic characterization.

Also, a follow-up conference for first responders will be held in March to discuss the chemical terrorism plan and the radiological terrorism plan and the operational plan developed to deal with these events if they occur.

West Nile Virus (WNV)

Laboratory-based surveillance for WNV resulted in testing 7,206 mosquito pools (115,494 individual mosquitoes) and 46 pools were positive for WNV; 1,871 birds were tested and 675 were positive for WNV; 129 horses tested and 31 positive resulting in 13 deaths; 694 humans tested with 13 confirmed cases of WNV.

WNV has been confirmed in every county except Somerset.

Newborn Screening for Hereditary Disorders

Screening newborn infants in Maryland for hereditary disorders by the public health laboratory at the time of discharge from the hospital has been one of the most successful public health prevention programs resulting in early detection and treatment of newborns with inherited disorders to prevent mental retardation, other disabilities or death. New scientific instrumentation is available to allow the laboratory to screen newborns for an additional 12 disorders for a total 21 disorders with the potential of preventing mental retardation.

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Response to Issues

Issue:

The Laboratories Administration should comment on outstanding emergency preparedness needs and anticipated future availability of federal funding.

Response:

Some Emergency Preparedness Needs That Still Exist:

- Additional staff is needed to test for increasing number of biological agents and for chemical and radiological terrorism agents.

- Continue training to strengthen the State Laboratory Response Network by hands-on-training of hospital personnel to recognize potential bioterrorism agents and the need to refer these agents to the State Public Health Lab for immediate confirmation.

- As additional potential biological agents are added to the list for rapid detection and identification the Laboratory will need to acquire some new instrumentation and training for staff to accurately identify these agents. For example, testing for the smallpox viruses requires special air filtration systems, special diagnostic techniques and enhanced building security.

- Equipment and space are needed to house an x-ray device to scan packages delivered to the lab for explosives, Geiger Counter to scan for radiation, and special biological safety cabinet with chemical filters to degas suspect packages before delivery to the lab personnel for examination for biological terrorism agents.

- Unfortunately, federal funding for bioterrorism preparedness is not expected to continue at the current level since funding was intended to help build laboratory infrastructure much of which was acquired with earlier grants. Also, failure to expend federal funds for positions provided in the bioterrorism grant may lead to further reduction in funding.

- New federal funding is expected to be available to build public health laboratory preparedness and response for chemical and radiological terrorism.

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Response to Recommended Actions

Recommendation:

1. Reduce growth in general funds for laboratory supplies. This action will still allow for a 5% increase in general funds for laboratory supplies over fiscal 2003 working appropriation ($190,250 GF).

Response:

DHMH disagrees with the recommendation to reduce laboratory supplies. The general fund increase for laboratory supplies over fiscal year 2003 is $252,466. Although this may represent more than 10% increase over fiscal 2003, it is important to retain these funds in the Laboratories Administration. In fiscal year 2003, two tandem mass spectrometers for newborn screening testing services were leased purchased through the State Treasurer for five years. This purchase allowed the Laboratories Administration to test for increased number of hereditary disorders in newborn babies. Consequently, this new technology caused a significant increase in the cost of laboratory supplies required for newborn screening services. It is estimated that the cost of supplies will double as a result of this new technology. The fiscal year 2004 allowance for newborn screening lab supplies is $450,324. We have already spent approximately $300,000 in the first six months of fiscal year 2003. It is imperative to retain these funds for laboratory supplies in order to cover increased costs in Newborn Screening Division.